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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/13/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,526

Applicant(s)

ABDUL MALAK ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002 and 14 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-45 and 50-64 is/are pending in the application.
- 4a) Of the above claim(s) 50-52 and 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 24-45 and 50-64 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to an amendments filed on May 28 and June 14, 2002.
2. In the amendment of May 28, 2002. Applicants added claims 59-64, and these will be considered as falling within the previously elected subject matter. Claims 21 and 46-49 were cancelled.
3. The pending claims are: 1-20, 22-45 and 50-64. Claims 50-52 and 55-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Response to Arguments

4. Applicant's arguments filed on June 14, 2002 have been fully considered but they are not persuasive. Applicant argues that the newly amended claims overcome the prior art rejections over Boyce, Eisenberg and the combination of these two references. However, the amended claims contain a Markush group of two products. The amended claims 1, 9, 20, and 61 (newly added in the amendment of May 28) are drawn to two products: a compact collagen membrane which is a collagen film prepared by drying a collagen gel and a compact collagen membrane which is a compressed collagen sponge prepared by a compression of a collagen sponge at a pressure of at least 50 bar. Therefore, even though the second product is not rejectable over prior art, the first one still is, and, in addition, the meaning of the term "compact" membrane, as applied to the first product, is unclear.

Therefore prior art rejections are maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19, 24-26, 28-38, 41-45, 53, 54 and 59-64 are rejected under 35 U.S.C. 112,

second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1, 5, 9, 12, 19, 28 and 34 are indefinite because of the limitation "...compact collagen membrane..." (emphasis added). It is unclear what properties of the membrane are described by this term.

B) Claim 2 is indefinite because of the limitation "...fluid selected from the group consisting of air and gas...". It is unclear why air and gas (what gas?) are categorized as "fluids".

C) Claims 3, 14, 15, 18, 24 recite the limitation "the collagen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

D) Claims 6 and 36 are indefinite because of the limitation "...cells originate substantially exclusively from young subjects...". It is unclear what the term "originate substantially exclusively means.

E) Claims 7 and 37 are indefinite because of the limitation "...cells originate substantially exclusively from elderly subjects...". It is unclear what the term "originate substantially exclusively means".

F) Claims 9 and 61 are indefinite because of the paragraph starting on line 9, which attempts to introduce product-by-process language into the claim and in the end it is totally unclear what has been added to the already present limitation of the porous layer comprising fibroblasts and the compact membrane comprising living cells.

G) Claim 16 recites the limitation "the membrane layer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

H) Claims 26 and 27 recite the limitation "said collagen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

I) Claims 28 and 34 recite the limitation "the compact membrane" in line 2. There is insufficient antecedent basis for this limitation in the claim.

F) Claims 44 and 53 are indefinite because of the limitation "...cells obtained substantially exclusively from ... young subjects...". It is unclear what the term "obtained substantially exclusively means.

G) Claims 45 and 54 are indefinite because of the limitation "...cells obtained substantially exclusively from ... elderly subjects...". It is unclear what the term "obtained substantially exclusively means".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-8, 12-20, 24-38, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (U.S. Patent No. 5,273,900).

Claims 10 and 11 were included in the product claim rejection as it is not clear what special properties are imparted to the composite by compression under pressure.

Boyce teaches a composite skin replacement comprising two components: an epidermal component and a porous, laminated dermal membrane. The dermal membrane is prepared from bovine collagen and a glycosaminoglycan (GAG), a polysaccharide. The membrane is covered with a laminating layer containing a mixture of collagen and GAG

(Abstract; col. 7, lines 7-16). The dermal membrane is then covered with normal keratinocytes (col. 7, lines 17-39).

To prepare the membrane, the membrane solution is frozen, lyophilized and cross-linked by physical or chemical means. Then a separately prepared gel of collagen and GAG is deposited onto the membrane, the two layers are frozen and lyophilized, then cross-linked using high temperatures and a vacuum or UV light. The laminated dermal membrane is then rehydrated and cross-linked with glutaraldehyde (col. 7, lines 40-62; col. 9, lines 17-66). Freezing is conducted in the freezing bath containing isopropanol or by using liquefied gases such as nitrogen, propane or air (col. 9, lines 25-36).

The dermal layer may be modified by an addition of biologically active molecules such as growth factors (col. 10, lines 1-5). The normal human keratinocytes are then inoculated into the dermal membrane, forming epidermal layer on the membrane's surface (col. 10, lines 45-54; col. 16, lines 26-32).

9. Claims 9, 43, 53, 54 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenberg (WO 91/16010).

Eisenberg teaches a composite skin equivalent comprising a porous cross-linked sponge matrix comprising living fibroblasts and a layer of non-porous collagen containing on its surface cultured keratinocyte cells. Both the fibroblasts and keratinocytes are obtained from skin samples (Abstract; page 5; page 6; first four paragraphs).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

Art Unit: 1637

subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce as applied to claim 20 above, and further in view of Eisenberg (WO 91/16010).

A) Claim 39 is drawn to introducing living fibroblasts into the porous layer.

B) Teachings of Boyce are described above. Boyce does not teach to introducing living fibroblasts into the porous layer.

C) Eisenberg teaches a composite skin equivalent comprising a porous cross-linked sponge matrix comprising living fibroblasts and a layer of non-porous collagen containing on its surface cultured keratinocyte cells. Both the fibroblasts and keratinocytes are obtained from skin samples (Abstract; page 5; page 6; first four paragraphs).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have prepared the porous layer of the skin replacement of Boyce with fibroblasts, as shown by Eisenberg. The motivation to do so, expressly provided by Eisenberg, would have been that such a skin equivalent closely resembled human skin in structure, where the fibroblasts are in the dermis and keratinocytes in the epidermis.

12. No references were found teaching or suggesting claims 10, 11, 22, 23, 59 and 60; claims 10, 11, 59 and 60 are rejected for other reasons. Claims 22 and 23 are objected as being dependent on the rejected claim 20.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
August 5, 2002

TS

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/6/02